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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,165	11/13/2003	Kevin R. Stone	CROL-132CPCN	8206

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,165	STONE ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *23-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 as amended (11/22/2006) are under examination.

Claims 23-48 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-46 of US 6,972,041 in view of Merck Index.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass substantially similar methods of making xenografts intended for human transplantation wherein the xenograft materials comprise "bone" of non-human animal and wherein the xenograft materials are treated with glycosidase and capping molecules as required by claimed methods.

Some of the claims of US 6,972,041 are drawn to the use of particular capping molecules such as fucosyl and glucosamine molecules, for example: claims 31-33. Some of the claims of the presently claimed invention are drawn to the use of particular capping molecules such as sialic acid molecules. However, the capping molecules such fucosyl, glucosamine and sialic acid are well known compounds widely distributed in animal mucoproteins and mucopolysaccharides as adequately demonstrated by The Merck Index (page 758 and page 1458). Thus, the claimed invention of US 6,972,041 and the presently claimed invention are obvious variants. Moreover, the instant invention is not intended to limit capping molecules to the exclusive use of sialic acid molecules (see specification page 13, line 7) and it encompasses the use of generic capping molecules including fucosyl and glucosamine in xenografts intended for human transplantation, for example: see claim 2 and see specification at page 11, lines 26-27.

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

2. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of US 6,455,309 in view of Merck Index.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass substantially similar methods of making xenografts intended for human transplantation wherein the xenograft materials comprise "bone" of "bone blocks" (see US 6,455,309 claims 22, 23 and 25, for example) or "bone" (instant application) of non-human animal and wherein the xenograft materials are treated with glycosidase and capping molecules as claimed.

Some of the claims of US 6,455,309 are broader and encompass xenografts such as ligament and/or articular cartilage that comprise bones or portion of bones or bone tissue (see claims 21-25, for example) as required for the presently claimed invention. The method of making xenograft products of US 6,455,309 comprises steps of treating xenograft materials with glycosidase and capping with molecules as required by the presently claimed method.

Some of the claims of US 6,455,309 are drawn to the use of particular capping molecules such as fucosyl and glucosamine molecules, fro example: claims18 and 19. Some of the claims of the presently claimed invention are drawn to the use of particular capping molecules such as sialic acid molecules. However, the capping molecules such fucosyl, glucosamine and sialic acid are well known compounds widely distributed in animal mucoproteins and mucopolysaccharides as adequately demonstrated by The Merck Index (page 758 and page 1458). Thus, the claimed invention of US 6,455,309 and the presently claimed invention are obvious variants. Moreover, the instant invention is not intended to limit capping molecules to the exclusive use of sialic acid molecules (see specification page 13, line 7) and it encompasses the use of generic capping molecules including fucosyl and glucosamine in xenografts intended for human transplantation, for example: see claim 2 and see specification at page 11, lines 26-27.

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

3. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 0f US 6,402,783 in view of Merck Index.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass substantially similar methods of making xenografts intended for human transplantation wherein the xenograft materials comprise block of "bone" (US 6,402,783) or "bone" (instant application) of non-human animal and wherein the xenograft materials are treated with glycosidase and capping molecules as claimed.

Some of the claims of US 6,402,783 are broader and encompass xenografts such as ligaments that comprise bones or some portion of bones or block of bones (see claims 9-10, for example) as required for the presently claimed invention. The method of making xenograft products of US 6,402,783 comprises steps of treating xenograft materials with glycosidase and capping with molecules as required by the presently claimed method.

Some of the claims of US 6,402,783 are drawn to the use of particular capping molecules such as fucosyl and glucosamine molecules, for example: claims 2 and 3. Some of the claims of the presently claimed invention are drawn to the use of particular capping molecules such as sialic acid molecules. However, the capping molecules such fucosyl, glucosamine and sialic acid are well known compounds widely distributed in animal mucoproteins and mucopolysaccharides as adequately demonstrated by The Merck Index (page 758 and page 1458). Thus, the claimed invention of US 6,402,783 and the presently claimed invention are obvious variants. Moreover, the instant invention is not intended to limit capping molecules to the exclusive use of sialic acid molecules (see specification page 13, line 7) and it encompasses the use of generic capping molecules including fucosyl and glucosamine in xenografts intended for human transplantation, for example: see instant claim 2 and see specification at page 11, lines 26-27.

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

4. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19, 21-15 and 58 of US 6,231,608 in view of Merck Index.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass substantially similar methods of making xenografts intended for human transplantation wherein the xenograft materials comprise "bone tissue" (US 6,231,608) or "bone" (instant application) of non-human animal and wherein the xenograft materials are treated with glycosidase and capping molecules as claimed.

Some of the claims of US 6,231,608 are broader and encompass xenografts such as ligament and/or articular cartilage that comprise bones or portion of bones or bone tissue (see claims 21-25, for example) as required for the presently claimed invention. The method of making xenograft products of US 6,231,608 comprises steps of treating xenograft materials with glycosidase and capping with molecules as required by the presently claimed method.

Some of the claims of US 6,231,608 are drawn to the use of particular capping molecules such as fucosyl and glucosamine molecules. Some of the claims of the presently claimed invention are drawn to the use of particular capping molecules such as sialic acid molecules. However, the capping molecules such fucosyl, glucosamine and sialic acid are well known compounds widely distributed in animal mucoproteins and mucopolysaccharides as adequately demonstrated by The Merck Index (page 758 and page 1458). Thus, the claimed

invention of US 6,231,608 and the presently claimed invention are obvious variants. Moreover, the instant invention is not intended to limit capping molecules to the exclusive use of sialic acid molecules (see specification page 13, line 7) and it encompasses the use of generic capping molecules including fucosyl and glucosamine in xenografts intended for human transplantation, for example: see claim 2 and see specification at page 11, lines 26-27.

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

5. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 US 6,210, 440.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass substantially similar methods of making xenografts intended for human transplantation wherein the xenograft materials comprise "bone" (instant application) or block of "bone" of non-human animal and wherein the xenograft materials are treated with glycosidase and capping molecules such as sialic acid as required by the claimed methods.

The claims of US 6,210, 440 are broader and encompass xenograft products such as ligaments which comprise bones or portion of bones (see claims 6, 7, 15, 16, for example). The whole xenograft products are treated with glycosidase and sialic acid molecules as claimed in the method of issued claims of US 6,210, 440 (B) and as required by presently claimed method of the instant application.

The claims of US 6,2 10, 440 are broader and include the presently claimed concentration ranges of sialic acid, for example: see claim 1 of US 6,210,440 and see instant claim 3. Some of

the claims of the instant application appear to be drawn to the use of concentration ranges of sialic acid which are identical to the sialic acid concentration in US 6,210, 440; for example: see claim 1 of US 6,2 10,440 and the instant claim 14.

Accordingly, the claimed methods and products are obvious variants. Thus, the inventions as claimed are co-extensive.

6. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of US 6,110,206.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass substantially similar methods of making xenografts intended for human transplantation wherein the xenograft materials comprise "bone" (instant application) or block of "bone" of non-human animal and wherein the xenograft materials are treated with glycosidase as required by the claimed methods.

The claims of US 6,110,206 are broader and encompass xenograft products such as ligaments which comprise bones or portion of bones (see claims 6 and 7, for example). The whole xenograft products are treated with glycosidase as claimed in the method of issued claims of US 6,110,206 and as required by presently claimed method of the instant application.

The claims of 6,110,206 are broader, they are not limited to the use of capping molecules and they are open to incorporation of additional steps or materials. On the other hand, some of the instant claims do not require the use of capping molecules, for example: see claim 1. In addition, the use of some generic capping molecules are intended for making the xenografts of US 6,110,206, for example: see col. 8, lines 13-16.

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

7. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of US 6,049,025.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass substantially similar methods of making xenografts intended for human transplantation wherein the xenograft materials comprise "bone" (instant application) or portion of "bone" of non-human animal and wherein the xenograft materials are treated with glycosidase and capping molecules including sialic acid as required by the claimed methods.

The claims of US 6,049,025 are broader and they encompass making xenografts such as ligaments that comprise bones or portion of bones (see claims 8 and 16, for example). The whole xenograft materials are treated with glycosidase in the method of issued claims and as required by presently claimed method of the instant application.

Some claims of US 6,049,025 are drawn to the use of concentration ranges of sialic acid which are identical to the presently claimed invention, for example: see claims 2 and 11 of US 6,049,025 and see the instant claim 14. Or the claims of US 6,049,025 are broader and include the presently claimed concentration range, for example: see the instant claim 3.

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

8. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of US 5,944,755 in view of Merck Index.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass substantially similar methods of making xenografts intended for human transplantation wherein the xenograft materials comprise block of "bone" (US 5,944,755) or "bone" (instant application) of non-human animal and wherein the xenograft materials are treated with glycosidase and capping molecules as claimed.

Some of the claims of US 5,944,755 are broader and encompass xenografts such as cartilage that comprise bones or portion of bones (see claim 8, for example) as required for the presently claimed invention. The method of making xenograft products of US 5,944,755 comprises steps of treating xenograft materials with glycosidase and capping with molecules as required by the presently claimed method.

Some of the claims of US 5,944,755 are drawn to the use of particular capping molecules such as fucosyl and glucosamine molecules, for example: claims 2 and 3. Some of the claims of the presently claimed invention are drawn to the use of particular capping molecules such as sialic acid molecules. However, the capping molecules such fucosyl, glucosamine and sialic acid are well known compounds widely distributed in animal mucoproteins and mucopolysaccharides as adequately demonstrated by The Merck Index (page 758 and page 1458). Thus, the claimed invention of US 5,944,755 and the presently claimed invention are obvious variants. Moreover, the instant invention is not intended to limit capping molecules to the exclusive use of sialic acid molecules (see specification page 13, line 7) and it encompasses the use of generic capping molecules including fucosyl and glucosamine in xenografts intended

for human transplantation, for example: see instant claim 2 and see specification at page 11, lines 26-27.

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

9. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of US 5,782,915.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass substantially similar methods of making xenografts intended for human transplantation wherein the xenograft materials comprise "bone" (instant application) or portion of "bone" of non-human animal and wherein the xenograft materials are treated with glycosidase.

Claims of 5,782,915 are broader and they encompass methods of making xenografts from articular cartilage comprising bones or portion of bones which are required for the presently claimed invention, for example: see claim 2. The issued claims of US 5,782,915 and the presently claimed invention are both drawn to methods of making xenografts that comprise bones or bone portions and that are treated with glycosidase in the methods of making xenografts.

The issued claims of 5,782,915 are broader, they are not limited to the use of capping molecules and they are open to incorporation of additional steps or materials. On the other hand, some of the instant claims do not require the use of capping molecules, for example: see claim 1.

In addition, the use of some generic capping molecules are intended for making the xenografts of US 5,782,915, for example: see col. 5, line 28.

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,231,608 (Stone), US 6,110,206 (Stone), US 6,049,025 (Stone et al), US 5,944,755 (Stone), US 5,782,915 (Stone) and US 5,922,027 (Stone) taken with Merck Index.

Claims are directed to methods of making xenografts intended for human transplantation wherein the xenografts comprise "bone" and/or portion of "bone tissue" of non-human animal and wherein the xenografts are treated with glycosidase and capping molecules. Some claims are/are further drawn to the use of capping molecules such as sialic acid molecules. Some claims are further drawn to the use of particular concentrations of sialic acid in the method of making xenografts. Some claims are further drawn to the use of glycosidase such as galactosidase, to the use of particular concentration of glycosidase, to the freeze/thaw cycles or gamma irradiation for cellular disruption, to the use of cross linking agents in the methods for making xenografts.

The cited patents are relied upon as explained above and they teach the similar concepts of making xenografts intended for human transplantation wherein the xenografts comprise "bone" and/or portion of bone tissue of non-human animal and wherein the xenografts are treated with glycosidase and capping molecules.

For example: US 6,1 10,206 discloses method of making ligament xenograft with the bone attached (see col. 5, lines 11-17) which is treated with glycosidase or alpha-galactosidase and with capping molecules (see examples 1 and 2).

US 5,944,755 discloses method of making articular cartilage xenograft comprising subchondral bone (see col. 5, lines 60-63) which is treated with glycosidase or alpha-galactosidase and with capping molecules (see examples 1 and 2).

US 5,782,915 teaches method of making articular cartilage xenograft comprising subchondral bone (see col. 4, lines 2 1-22) which is treated with glycosidase (col. 6, line 34) and with capping molecules (col. 5, line 28).

US 5,922,027 teaches method of making an articular cartilage xenograft comprising subchondral bone (see col. 4, lines 23-26) which is free from moieties susceptible to glycosidase digestion (col. 7, line 12) and which is treated with capping molecules (col. 5, line 32).

The cited patents further teach the use of freeze/thaw cycles or gamma irradiation for cellular disruption, the use of cross-linking agents in the methods for making xenografts. For example: See US 6,110,206 at col. 5, 1ines-36, 46 and 62; or See US 5,944,755 at col. 6, lines 17, 28 and 44; or See US 5,782,915 at col. 4, lines 57 and 67; or See US 5,922,027 at col. 4, line 53 and col. 5, line 2.

The cited patents teach the use of various capping molecules in the method of making xenografts including capping molecules such as glucosamines, for example: see US 6,110,206 at col. 8, lines 15-16; or see US 5,944,755 at col. 9, lines 9-11. But the cited patents are silent with regard to the use of sialic acid.

However, the Merck Index teaches that the capping molecules such as glucosamine and sialic acid are well known compounds which are widely distributed in animal mucoproteins and mucopolysaccharides, for example: page 758 and 1458.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use various capping molecules in the method of making xenografts with a reasonable expectation of success in making xenografts suitable for transplantation because various capping molecules including glucosamine and sialic acid are widely distributed in mucoproteins and mucopolysaccharides of animal tissues and, thus, they considered to be biochemically functional equivalents.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 11/22/2006 have been fully considered but they are not persuasive.

With regard to the claim rejections on the ground of nonstatutory obviousness-type double patenting applicants intention to file terminal disclaimers is noted (response page 8).

With regard to the claim rejection under 35 USC § 103 applicants arguments are based on unsigned declaration that the cited patents are not inventions "by another". Yet, the inventive entities of the instant applicant and the cited patents are different and, thus, the cited patents are inventions "by another".

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

February 13, 2007

VERA AFREMOVA

PRIMARY EXAMINER